

Notice of Allowability	Application No.	Applicant(s)	
	10/726,224	M. SAUNDERS, ALEX	
	Examiner	Art Unit	
	Gary W. Counts	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to communication filed 12/01/03.
2. ☒ The allowed claim(s) is/are 1-19.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>07/02/04</u> . |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date <u>02/25/04</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Eric Whitt on July 2, 2004.

IN THE SPECIFICATION:

On page 1, paragraph 0001 after the recitation "patent application 09/976,235" inserted --"now Patent No. 6,682,903"--.

IN THE CLAIMS:

Claim 1, part (c) after the recitation "presence" inserted --or amount--.

2. The following is an examiner's statement of reasons for allowance: the cited references of record do not teach nor suggest the step of chemically combining a first product and a second product wherein the products produce a colored reaction product. Nor do the cited references of record teach or suggest adding two separate substrates to act on the two enzymes to produce the two colorless products, which chemically combine to produce the colored reaction product.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

The closest reference is Clemmons (US 5,637,473). Clemmons teaches a liquid-phase immunodiagnostic assay comprising first and second enzymes, a first agent which binds with an analyte to form a complex, wherein the first agent is attached to one of the first and second enzymes and a complex-binding agent attached to the remaining enzyme, wherein the first enzyme interacts with a substrate for the first enzyme for the first enzyme to produce a substrate for the second enzyme (col 2, lines 37-54).

Clemmons also teaches the use of a scavenger. However, Clemmons fails to teach or suggest the step of chemically combining a first product and a second product wherein the products produce a colored reaction product.

Akhavan-Tafti et al (US 5,843,666) disclose a method for determining an analyte in solution comprising a first antibody (ligand) labeled with alkaline phosphatase and a second antibody (ligand) labeled with horseradish peroxidase. Akhavan-Tafti et al disclose that these two labeled antibodies are used in a sandwich assay to determine the analyte (col. 8, lines 14-27). Akhavan-Tafti et al disclose that the alkaline phosphatase is used to cleave a substrate to produce an enzymatic reaction product. Akhavan-Tafti et al disclose the horseradish peroxidase oxidizes a second substrate to produce an enzymatic reaction product. Akhavan-Tafti et al further disclose that the combined action of both a hydrolytic enzyme and a peroxidase enzyme, which are maintained in a closely spaced relationship to each other, operates to produce a detectable chemiluminescent signal. However, Akhavan-Tafti et al fails to teach or suggest the analyte has enzymatic activity and also fails to teach or suggest the step of chemically combining (form a covalent chemical linkage, as defined on pages 11 and 12

Art Unit: 1641

in applicants specification) a first product and a second product wherein the products first and second products produce a colored reaction product.

DiNello et al (US 4,687, 735) disclose an immunoassay channeling involving one, usually two enzymes where the enzymes are related by the product of one enzyme being the substrate of the other enzyme. However, DiNello et al does not teach nor suggest the step of chemically combining a first product and a second product wherein the products produce a colored reaction product. Nor does DiNello et al teach or suggest adding two separate substrates to act on the two enzymes to produce the two colorless products, which chemically combine to produce the colored reaction product.

Conclusion

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Asgari et al (US 5,861,253) teaches the detection of Fetal hemoglobin (analyte having enzymatic activity) (abstract). Asgari et al disclose detection can be performed by using labeled enzyme and a substrate (col 3).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1641

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gary W. Counts
Examiner
Art Unit 1641
July 2, 2004



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

07/12/04